PATENT COOPERATION TREATY

PCT

REC'D 31 JAN 2005
WIPO PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 15632PCT00	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/DK 03/00698	International filing date *(day/month/year)* 14.10.2003	Priority date *(day/month/year)* 14.10.2002
International Patent Classification (IPC) or both national classification and IPC A61F2/06		
Applicant CUBE MEDICAL A/S et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
13.05.2004	27.01.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 pmu d Fax: +49 89 2399 - 4465	Authorized Officer Portoni, L Telephone No. +49 89 2399-2345

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/DK 03/00698

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-10 as originally filed

Claims, Numbers

1-34 received on 11.10.2004 with letter of 11.10.2004

Drawings, Sheets

1/7-7/7 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. N n-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 1-22

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 1-22 are so unclear that no meaningful opinion could be formed *(specify)*:

   see separate sheet

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	23-34
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	23-34
Industrial applicability (IA)	Yes:	Claims	23-34
	No:	Claims	

2. Citations and explanations

s e separate sheet

R It m III
Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The amendments introduced in claim 1 with letter of 11.10.2004 render the subject-matter of said claim so unclear that it is not possible to give a reasoned opinion on the novelty, inventive step or industrial applicability of the claimed subject-matter.
The reason therefore is that in amended claim 1 the applicant attempts to define the stent assembly by defining process steps of its method of manufacture rather than clearly defining the apparatus in terms of its technical features. The intended limitations are therefore not clear from this claim, contrary to the requirements of Article 6 PCT.
At the moment, the only deriving technical features that the skilled person can consider to be implied by the definition in the characterising portion of amended claim 1 are that the fabric has a tubular shape with an inner diameter smaller than the outer diameter of the stent in its unexpanded condition.
The attention of the applicant is drawn to documents WO 02 24247 A (D3) and WO 02 49535 A (D1), which appears to be very relevant for the subject-matter of amended claim 1 (see in particular in D3, from line 18, page 13, to line 17, page 14; page 18, lines 12-21; page 29, lines 15-30; in D1, see in particular page 16, lines 12-23)
Claims 2-22 also don't meet the requirements of Article 6 PCT, due to their dependency from claim 1.

R Item V
R asoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Document WO 02 24247 A (D3), representing the closest prior art, discloses a method of manufacture of a stent assembly comprising the steps of manufacturing the stent and applying a cover to the stent (see from line 18, page 13, to line 17, page 14) wherein the cover is preformed into the shape of a tube before the cover is applied to the stent (see page 18, lines 12-21; page 22, lines 14-15; page 29, lines 15-19 page 51, last paragraph) the step of applying the cover to the tube comprising placing the unexpanded stent into the cover tube, the cover tube having an inner diameter which is smaller than the outer diameter of the stent when the tube is placed on the stent to achieve an inward gripping action of the cover tube on the unexpanded stent (see page 29, lines 19-30).
The method of manufacture of the present international application differs from the method described in document D3 in that the cover of the stent assembly is a

fabric.
The use of a cover with the openness of the fabric construction provide a stent assembly which characteristics may be better varied to suit the circumstances and the special medical application (for instance vessel with side branches or not).
However, the method defined in claim 23 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) because the use of a fabric cover in the manufacture of a similar stent assembly has already been disclosed in document WO 02 49535 A (D1) (see in particular page 16, lines 12-23).
Therefore, the present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 23 does not involve an inventive step in the sense of Article 33(3) PCT.

2. Dependent claims 24-34 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, the reasons being as follows.

- The additional features of claims 24, and 32-34 have been disclosed in document D3 as well (see page 29, lines 15-39; page 13, lines 20-28; figures 11a-12b; page 52, lines 9-15).
- The feature of dependent claim 25 is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.
- The features of dependent claims 26-31 are known from document D1 (see in particular page 3, lines 1-3; page 16, lines 21-23; page 25, lines 9-19; see also the examples from page 26 on).

Further observations

- Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D3 is not mentioned in the description, nor are these documents identified therein.
- Independent claims are not drafted in the two-part form in accordance with Rule 6.3(b) PCT, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

International application No. PCT/DK03/00698
Publication No. WO 2004/034931

NEW CLAIMS, 11 OCTOBER 2004

1. A stent assembly comprising a tubular stent, an external surface of which is provided with a fabric, characterized in that the fabric has been pre-formed into the shape of a tube, into which the stent has been placed in the unexpanded state of the stent, the fabric tube having an inner diameter which is smaller than the outer diameter of the stent when the tube is placed on the stent to achieve an inward gripping action of the fabric tube on the unexpanded stent.

2. A stent assembly according to claim 1, wherein the fabric tube has been manufactured with an inner diameter which is smaller than the outer diameter of the unexpanded stent.

3. A stent assembly according to claim 1, wherien the fabric tube has been longitudinally folded to a smaller diameter than the outer diameter of the stent when fitted over the unexpanded stent.

4. A stent assembly according to any of the preceding claims, wherein the fabric constitutes a reservoir to hold drugs.

5. A stent assembly according to any of the preceding claims, wherein the fabric is made from a filamentary material.

6. A stent assembly according to claim 5, wherein the filamentary material includes at least one polymer.

7. A stent assembly according to claim 6, wherein the at least one polymer is selected from the group consisting of: polyurethane, polyamide, gelatine, silicone and agar.

8. A stent according to any of claims 5-7 wherein the fabric is made from a multifilament yarn.

9. A stent assembly according to any of the claims 5-7, wherein at least a portion of the fabric is produced by spinning of nanofibers.

10. A stent assembly according to claim 9, wherein said portion is produced by electrospinning.

11. A stent assembly according to claim 9 or 10, wherein the diameter of the nanofibers is in the range of 2 to 4000 nanometers, such as in the range of 2 to 3000 nanometers.

12. A stent assembly according to any of claims 9-11, wherein the nanofibers are made from a polymer.

13. A stent assembly according to claim 12, wherein the nanofibers are made from a material selected from the group consisting of: nylon, fluoropolymers, polyolefins, polyimides, and polyesters.

14. A stent assembly according to any of the preceding claims, wherein the fabric has an openness which allows the fabric to serve as a reservoir for liquid-based drugs.

15. A stent assembly according to any of the preceding claims, wherein the tubular stent comprises an assembly of radially expandable, tubular elements aligned along a common longitudinal axis and successively joined together in pairs by respective sets of linking members.

16. A stent assembly according to claim 15, wherein each tubular element exists essentially of a strip forming a zigzag corrugation.

17. A stent assembly according to any of the preceding claims, wherein the fabric completely covers the cylindrical external surface of the stent.

18. A stent assembly according to any of the preceding claims, wherein the stent is crimped onto a balloon for expanding the stent.

19. A stent assembly according to any of the preceding claims, wherein the stent is auto-expandable.

20. A stent assembly according to claim 19, wherein the stent is made essentially from a material selected from the group consisting of: stainless steel, Phynox®, and nitinol.

21. A stent assembly according to any of claims 1-18, wherein the stent is expandable by forced expansion, the stent being made essentially from a metallic material.

22. A stent assembly according to claim 21, wherein the metallic material is selected from the group consisting of: tungsten, platinum, tantalum, gold, and stainless steel.

23. A method of manufacturing a stent assembly according to any of the preceding claims, comprising the steps of:
- manufacturing the stent;
- applying the fabric to the stent, characterized in that
the fabric is preformed into the shape of a tube before the fabric is applied to the stent, the step of applying the fabric to the stent comprising placing the unexpanded stent into the fabric tube, the fabric tube having an inner diameter which is smaller than the outer diameter of the stent when the tube is placed on the stent to achieve an inward gripping action of the fabric tube on the unexpanded stent.

24. A method according to claim 23, wherein the fabric tube is preformed with an inner diameter which is smaller than the outer diameter of the unexpanded stent.

25. A method according to claim 23, wherein the step of applying the fabric tube to the stent comprising longitudinally folding the fabric tube to a smaller diameter than the outer diameter of the unexpanded stent.

26. A method according to any of claims 23-25, wherein the fabric is manufactured by spinning of nanofibers.

27. A method according to claim 26, wherein the step of spinning comprises electrospinning.

28. A method according to claim 26 or 27, wherein the diameter of the nanofibers is in the range of 2 to 4000 nanometers.

29. A method according to any of claims 26-28, wherein the step of spinning comprises feeding a first fiber-forming material into a nozzle for forming nanofibers by using a pressurized gas stream, and ejecting the first fiber-forming material from an exit orifice of the nozzle in the form of a plurality of strands of said first fiber-forming material that solidify and form said nanofibers.

30. A method according to any of claims 26-29, wherein the nanofibers are made from a polymer.

31. A method according to claim 30, wherein the nanofibers are made from a material selected from the group consisting of: nylon, fluoropolymers, polyolefins, polyimides, and polyesters.

32. A method according to any of claims 23-31, wherein the stent is manufactured from a hollow tube, in which a pattern of tubular elements and linking elements is formed.

33. A method according to any of claims 23-31, wherein the step of manufacturing the stent comprises rolling up of a sheet of material to form the tube, and securing adjoining edge portions of the sheet together.

34. A method of preparing a stent assembly according to any of claims 1-22, comprising the step of providing a drug to the fabric.